

As admitted in the Office Action, Dorman teaches nothing regarding methods for forming additional pores in a particulate-leached material by gas foaming. Dorman, therefore, also cannot teach polymer materials which contain porosity resulting from both particulate leaching and of gas foaming.

The position apparently taken in the Office Action is that it was known in the art to form pores in a polymer material by gas foaming and, therefore, it would have been obvious to form pores by gas foaming in the Dorman materials, in addition to the porosity already formed therein by particulate leaching. No reference is cited to evidence such alleged obviousness of the gas foaming. On the record, the only suggestion for performing gas foaming together with particulate leaching comes from applicants' own disclosure, the use of which is improper to support a 35 U.S.C. § 103 rejection. This lack of evidence on the record, itself, is a convincing basis for withdrawal of the rejection. But the following additional reasons are provided for withdrawal of the rejection.

Even if the record did evidence art recognition of gas foaming to form porosity in polymers, it is a well established tenet of patent law that an invention directed to a combination of old elements is not obvious under 35 U.S.C. § 103 unless there is a suggestion in the art to combine those old elements. See, e.g., In re Fine, 5 USPQ 2d 1596,1598-99 (Fed. Cir. 1988), stating “[b]efore the PTO may combine the disclosures of two or more prior art references in order to establish prima facie obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.” See also, In re Rouffet, 47 USPQ 2d 1453 (Fed. Cir. 1998), further discussing the need for motivation to combine art-known elements. Thus, even if it is assumed gas foaming of polymers to make them porous was known in the art, there is no suggestion from the prior art of record to combine a method of

forming porosity by particulate leaching (as in Dorman) and by gas foaming. The combination of porosity forming by each of the two methods provides materials with two types of porosity providing a novel pore structure. There is no suggestion from the art of a material which combines such or why such a combination of two types of porosity would be desired.

Dorman certainly provides no suggestion of conducting additional steps of gas foaming its materials to generate additional porosity therein. To the contrary, since Dorman is directed to materials for hard tissue prosthetics, such as bone, the initial direction to one of ordinary skill in the art would be to not form additional porosity because it would be expected to weaken the material. Also, there is certainly no suggestion from any art directed to gas foaming methods to combine such methods with particulate leaching methods for the simple reason that no art on gas foaming methods has been relied upon in the rejection. Thus, the only suggestion for combining the two types of porosity forming methods and provide a single material with both types of resulting porosity improperly comes from applicants' own disclosure. See, e.g., page 3, line 7, to page 5, line 15, describing the novel features of the invention and the advantages thereof not realized by the prior art.

It is urged that, in the absence of any suggestion in the art that it would have been desirable to modify a polymer having porosity from particulate leaching to provide additional porosity from gas foaming, the instant claims are not obvious. For this additional reason, no prima facie case of obviousness is supported and the rejection under 35 U.S.C. § 103 should be withdrawn.

The nonobviousness of certain dependent claims is even further evident. As to claims 25-26, 28-29 and 34-36, Dorman provides no teachings, whatsoever, suggesting incorporation of a drug or cells within its polymer material. As to claims 30-33, Dorman

provides no teaching or suggestion of connecting a portion of impermeable polymer with the porous materials. No references are cited to support obviousness of the additional recitations of these claims and no reasons are given as to why one of ordinary skill in the art would be **motivated** to modify Dorman to meet these aspects. Thus, there is additional basis for lack of a prima facie case of obviousness as to these claims.

Although such is unnecessary due to the absence of a prima facie case of obviousness, as discussed above, applicants do provide evidence in their specification showing the unexpected advantages of their invention. Thus, further supporting the nonobviousness thereof. On page 20 to page 21, the specification discusses the nature of the materials, as observed by photomicrographs, prepared by a combination of gas foaming and particulate leaching (GF/PL), according to applicants' invention, and those prepared by only gas foaming or only by particulate leaching (SC/PL), the latter as in Dorman. Gas foaming alone results in a largely closed pore structure and particulate leaching alone results in a non-uniform porosity. To the contrary, the GF/PL materials of applicants' invention exhibit a stable, uniform porosity with a significant open pore structure. Additionally, the GF/PL materials of applicants' invention and the SC/PL materials representative of Dorman were tested side-by-side for their mechanical properties. Applicants' materials exhibited significantly improved compressive and tensile modulus; see, e.g., Table I, page 22, and Figure 1. Examples 2-4 of applicants' specification show the further advantageous use of applicants' materials, particularly in the ability to incorporate and release growth factors due to their open porosity.

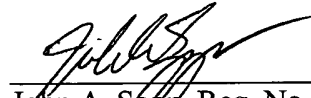
The above-discussed advantages of applicants' method and resulting polymers could not have been expected from the prior art cited in the Office Action. Thus, further proof of the nonobviousness of applicants' invention is provided.

For all of the above reasons, it is respectfully submitted that Dorman, considered as a whole, fails to render any of the instant claims obvious to one of ordinary skill in the art. Thus, the rejection under 35 U.S.C. § 103 should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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